

Hemp-Derived Cannabinoids





HEMP-DERIVED CANNABINOIDS

Concerns & Challenges

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Hemp Overview (How We Got Here)

Federal Definition

The Agricultural Improvement Act of 2018 (2018 Farm Bill) authorized the production of hemp and hemp-derived compounds within the United States. It defined hemp as, "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis" (7 USC § 16390 (1) HEMP).

The cannabis plant naturally contains over 100 cannabinoids with delta 9 tetrahydrocannabinoid (D9-THC) being the predominant intoxicating cannabinoid in the plant. The 2018 Farm Bill's definition of hemp outlines the amount of D9-THC as the key differentiator between hemp and all other cannabis products, such as marijuana. Marijuana is listed on the Drug Enforcement Administration's (DEA) schedule of Controlled Substances and is federally illegal.

The 2018 Farm Bill's broad definition of hemp has created "loopholes", whether real or perceived, allowing for the legal production of intoxicating hemp-derived products by:

- 1. Quantifying D9-THC potency by weight.
 - a. This means commodities created with hemp-derived cannabinoids have the potential to become intoxicating as the manufactured product weight increases because the weight of an infused product is significantly greater than dried hemp flower.
- 2. *Not* limiting any other cannabinoid, whether naturally occurring or chemically created.
 - This means traditionally non-intoxicating cannabinoids, such as Cannabidiol (CBD), can be "chemically converted" to intoxicating cannabinoid using basic chemistry.
 - b. This also means THCA, the precursor to intoxicating D9-THC, is widely used in hemp products. THCA easily converts to D9-THC when heated, such as by smoking flower or via vaping.
 - c. Intoxicating hemp-derived compounds created through chemical conversion have not been widely studied for safety in human consumption.

Federal Hemp and Hemp-derived Compound Regulation

Currently, the U.S. Department of Agriculture (USDA) regulates hemp production and states may defer to the USDA to license their hemp growers. Missouri has deferred to the USDA. The USDA regulatory framework includes testing hemp producer crops for potency to ensure they comply with the D9-THC limit for hemp. However, the **USDA's regulatory authority ends after harvest**.

The Food and Drug Administration (FDA) has the authority to regulate cannabis or cannabis-derived compounds in drugs, foods, dietary supplements, and cosmetics under the Federal Food, Drug, & Cosmetic Act and section 351 of the Public Health Service Act (PHS Act). This means any cannabis-derived compound is subject to the same authorities and requirements as FDA-regulated products containing any other substance, including any applicable ingredient application, review, and approval. The FD&C Act does not provide the FDA with authority to protect consumers of inhalable or combusted products, a common way of introducing cannabinoids into the human body.

Overall, the FDA views cannabis-derived cannabinoids as prohibited additives in foods and dietary supplements. However, it has not taken significant action to enforce this prohibition.

Health and Safety Concerns (The Problem)

Currently, a wide variety of foods, beverages, dietary supplements, and other commodities containing hemp-derived compounds, both intoxicating and non-intoxicating, are available online and in traditional brick-and-mortar establishments, including in Missouri. Without the federal oversight that would normally be applied to such commodities, there is no framework in place to address or mitigate the known health and safety concerns with these commodities.

Potential for Unexpected Intoxication

There are no federal standards requiring products containing hemp-derived compounds to disclose the amount of D9-THC, or any other intoxication cannabinoid, in a product. One recent study found at least twenty-six different intoxicating compounds in hemp-derived cannabis products readily available on the market, the most common being Delta-8 tetrahydrocannabinol (THC), THC-P, Delta-9 THC, HHC, THC-A, Delta-10 THC, THC-H, THC-B, THC-JD, THC-X, HHC-P, and Delta-11 THC.

Unintentionally consuming D9-THC or other intoxicating cannabinoids from products containing hemp-derived compounds may cause a host of problems for consumers, such as:

- Consumers subject to drug testing, for example through their job or as a condition of probation, may fail due to unintentionally consuming D9-THC.
- Consumers operating vehicles or heavy machinery may become unexpectedly intoxicated, and extremely dangerous, due to unintentionally consuming intoxicating cannabinoids.
- Children may become unexpectedly intoxicated and need emergency care due to consuming products that they or their caregivers are unaware contain intoxicating cannabinoids.

Appeal to Children and Mimicking of Commercial Food Products

Federal regulations do not impose age restrictions on intoxicating hemp-derived products, which are widely available online and in brick-and-mortar establishments like gas stations, grocery stores, and convenience stores. Some of these intoxicating hemp-derived products intentionally mimic commercial food products that appeal to children. Between January 1, 2021, and February 28, 2022, national poison control centers received 2,362 exposure cases of delta-8 THC products. Of the 2,362 exposure cases 40% involved unintentional exposure to delta-8 THC, and 82% of those affected were pediatric patients less than 18 years of age. In 2018, the Missouri Poison Center received seven calls related to cannabis exposure in children five and under. By 2023, that number was 168. Emergency Department and inpatient admission for cannabis poisoning are also on the rise for all ages. See Appendix A for data related to Missouri cannabis poisoning incidents.

Contaminants

Contaminants in cannabis products can jeopardize consumer health and safety. Unlike products in regulated state marijuana programs, hemp-derived products are not required to undergo a robust screening to help ensure consumer health and safety. These contaminants can enter hemp-derived products at any point in their creation, from cultivation through final product packaging.

It is standard practice in state marijuana regulation to require that all final marijuana product pass the following mandatory contaminant testing prior to sale:

- Microbial Screening
- Chemical Residue Screening
- Heavy Metal Screening
- Residual Solvent Screening
- Water Activity and Moisture Content Screening
- Foreign Matter Screening

One of the most common tests for cannabis plants to fail simply due to the nature of the plant is heavy metal screening. Hemp-derived products are not subject to required testing for heavy metals, and even where producers claim they test their products, there is no oversight of the testing process or results to know whether the products have been appropriately tested. Perhaps most important, there is no scientific regulatory authority setting "safe for human consumption" limits for contaminants in hemp-derived products in order for any producer to say they have met an established health standard.

Chemically Converted Cannabinoids

Chemically converted hemp-derived cannabinoids, which are included in almost every hemp-derived intoxicating product on the market today, have not been widely studied for safety in human consumption. Some of the converted cannabinoids are new compounds not found in nature.

The process of chemically converting hemp-derived cannabinoids involves a wide range of solvents and reagents. If hemp-derived product manufacturers do not take precautions to remove any residual solvents or reagents, a consumer may become exposed at an unsafe level, and only the manufacturer can know what solvents or reagents need to be removed. It is not feasible to generate a comprehensive list of solvents and reagents used by all manufacturers due to the wide variety that may be used to create different chemically converted cannabinoids.

Additionally, in nearly every chemical reaction, an amount of side-reaction product will be created. The chemical byproducts are often unpredictable and harmful. However, the scope of the potential toxicity of the side-reaction products remains largely unknown. Side-reaction products differ depending on the reaction conditions such as reagents, solvents, temperature, pressure, and atmosphere. And again, it is not feasible to identify all side-reaction products of concern due to the wide variety that may be created using different solvents and reagents.

Missouri's Regulatory Challenges

States across the nation are adopting a range of standards relating to warning labels, packaging, minimum age of sale, manufacturing and testing, ingredient prohibitions, adverse event reporting and recalls. State regulations for hemp often mirror existing regulations for state marijuana programs since hemp and marijuana both come from the cannabis plant. Alternatively, and due to the unique health risks associated with chemical conversion of cannabinoids, some states have chosen to prohibit intoxicating hemp-derived cannabinoids. See Appendix B for brief summaries of regulatory frameworks for these products in other states. There is currently no regulatory framework in Missouri for these products.

Missouri Regulation of Food

The Bureau of Environmental Health Services (BEHS) within the Department of Health and Senior Services (DHSS) has the responsibility of administering food safety in Missouri. Missouri's food safety operations are closely aligned with the US Food and Drug Administration (FDA) food safety framework. This alignment is in part due to 196.045, RSMo, which authorizes and requires DHSS to establish food regulations for efficient enforcement and that conform, insofar as practicable, with the federal act, and to 196.050, RSMo, which indicates that the DHSS may not prescribe more stringent regulations than prescribed by the federal act.

In addition, food safety operations in BEHS are predominately funded by the FDA, and as such, BEHS operations must coincide with federal law. In order to be eligible for those federal funds, BEHS staff must be credentialed officers of the FDA and act in accordance with federal regulations. The FDA's position is that it is unlawful for CBD or THC to be added to a food or marketed as a dietary supplement entering interstate commerce. 21 U.S.C. 331(II) prohibits the introduction or delivery for introduction into interstate commerce any food to which has been added a substance which is an active ingredient in a drug product that has been approved under 21 USC 355, or a drug for which substantial clinical investigations have been instituted and for which the existence of such has been made public. The FDA has concluded that it is prohibited to introduce or deliver for introduction into interstate commerce any food to which THC (including non-delta-9 THC) or CBD has been added. However, 196.070(2) prohibits DHSS from finding a food to be adulterated solely for containing industrial hemp, or an industrial hemp commodity or product. This leaves DHSS in a precarious position in trying to uphold federal law while simultaneously abiding by state law, as many of the products in the Missouri market contain industrial hemp, or an industrial hemp commodity or product, utilizing CBD or THC made from CBD.

Missouri Regulation of Marijuana

Article XIV of the Missouri Constitution allows for the regulation of marijuana and marijuana-derived compounds but excludes from this regulation all commodities made from hemp. Therefore, DHSS does not have any regulatory authority over products containing *only* hemp or hemp-derived compounds.

DHSS does have regulatory authority over hemp or hemp-derived compounds added to marijuana products. By rule, and in order to protect the public health, regulated marijuana products may not contain hemp-derived compounds made through chemical modification, conversion, or synthetic derivation to produce intoxicating cannabinoids (19 CSR 100-1.170(2)(F)).

Currently, many unregulated intoxicating hemp-derived products are available for sale within Missouri. See Appendix C for some examples available for purchase in local brick-and-mortar retail establishments within Jefferson City and Columbia, MO.

Appendix A - Cannabis Poisoning Data

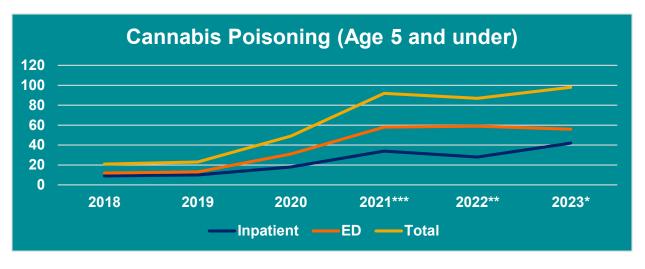
Cannabis Poisoning – Age 5 and Under

Patient Abstract System - Missouri Department of Health and Senior Services

DHSS has seen an increase in children who sought treatment in a hospital or emergency room setting. The below data is from the Patient Abstract System, which comes from patient visits to hospitals for treatment. This is similar to increases seen by the Missouri Poison Center, which is presented below.

CANNABIS POISONING (AGE 5 AND UNDER)

	<u>2018</u>	<u>2019</u>	2020	2021***	2022**	<u>2023*</u>	<u>Total</u>
Inpatient	9	10	18	34	28	42	141
ED	12	13	31	58	59	56	229
Total	21	23	49	92	87	98	370



- *** First full year of cannabis sales (medicinal)
- ** Provisional data not yet finalized
- * Data counts based on partial year (January through September)

POISON CONTROL CALLS (AGE 5 AND UNDER)

Year	<u>2018</u>	<u>2019</u>	<u>2020</u>	<u>2021</u>	<u>2022</u>	<u>2023</u>	<u>Total</u>
Count	7	26	57	102	125	168	485

Cannabis Poisoning – All Ages

Patient Abstract System – Missouri Department of Health and Senior Services

Emergency Department (ED)							
Age	<u>2018</u>	<u> 2019</u>	<u> 2020</u>	<u> 2021</u>	2022**	<u>2023*</u>	<u>Total</u>
Under 6	12	13	31	58	59	56	229
6 to 12	3	6	16	22	17	22	86
13 to 20	40	64	65	52	83	60	364
Total Pediatric Cases	55	83	112	132	159	138	679
Adult Cases	86	173	166	171	137	138	871
Total Cases	141	256	278	303	296	276	1550

Inpatient							
Age	<u>2018</u>	<u> 2019</u>	<u>2020</u>	<u> 2021</u>	2022**	<u>2023*</u>	<u>Total</u>
Under 6	9	10	18	34	28	42	141
6 to 12	2	1	4	4	5	9	25
13 to 20	10	16	11	9	8	5	59
Total Pediatric Cases	21	27	33	47	41	56	84
Adult Cases	75	96	56	44	25	42	479
Total Cases	96	123	89	91	66	98	563

All Hospital Data (Inpatient and ED)							
<u>Age</u>	<u>2018</u>	<u>2019</u>	<u>2020</u>	<u>2021</u>	<u>2022**</u>	<u>2023*</u>	<u>Total</u>
Under 6	21	23	49	92	87	98	370
6 to 12	5	7	20	26	22	31	111
13 to 20	50	80	76	61	91	65	423
Total Pediatric Cases	76	110	145	179	200	194	904
Adult Cases	161	269	222	215	162	180	1209
Total Cases	237	379	367	394	362	374	2113

^{**} Provisional data not yet finalized
*Data counts based on partial year only (Jan through September)

Appendix B – Hemp-derived Cannabinoid Regulation in Other States

State	Intoxicating Hemp-derived Cannabinoid Regulation
Arkansas	Chemically converted cannabinoids are prohibited.
Colorado	 Department of Public Health & Environment (CDPHE) regulates hemp products. Have authority to allow or prohibit production of semi- or synthetic cannabinoids from hemp. Have THC mg serving size and THC per package limit for hemp products. Have age verification in place for certain cannabinoid hemp products
Connecticut	 Marijuana regulatory authority oversees hemp product manufacturing and testing standards. Expanded THC definition to include chemically converted cannabinoids.
Florida	 Most hemp products are regulated by the Florida Department of Agriculture and Consumer Services. Hemp topicals are regulated by the Florida Department of Business and Professional Regulation. Chemically converted cannabinoids are a Schedule I substance.
Louisiana	 Marijuana regulatory authority regulates hemp product the same as marijuana. Chemically converted cannabinoids are prohibited. Have THC mg serving size and THC per package limit for hemp products. Have age verification in place for certain cannabinoid hemp products.
Maryland	 Maryland Department of Agriculture licenses industrial hemp growers and processors. Have THC mg serving size and THC per package limit for hemp products. Have age verification in place for certain cannabinoid hemp products.
Massachusetts	 Massachusetts Department of Agricultural Resources (MDAR) retains jurisdiction over the licensing of hemp. Chemically converted cannabinoid products are subject to the same testing requirements for Marijuana and Marijuana Products. Have THC mg serving size and THC per package limit for hemp products. Have age verification in place for certain cannabinoid hemp products
Michigan	 Marijuana regulatory authority oversees hemp product processing and products.

State	Intoxicating Hemp-derived Cannabinoid Regulation
Nevada	 Not allowed in marijuana licenses. POST officers work with local jurisdictions for non-marijuana establishments. Expanded THC definition to include chemically converted cannabinoids.
New Hampshire	 Hemp-derived products containing THC prohibited; including chemically converted cannabinoids
New York	 Marijuana regulatory authority oversees hemp products. Chemically converted cannabinoids are prohibited. Have THC mg serving size and THC per package limit for hemp products. Have age verification in place for certain cannabinoid hemp products
Oregon	Marijuana regulatory authority oversees hemp products.
Rhode Island	 Marijuana regulatory authority oversees hemp products. Have age verification in place for certain cannabinoid hemp products.
Utah	 Utah Department of Agriculture and Food regulate hemp products. Requires chemically converted cannabinoids to meet a purity standard. Have THC mg serving size and THC per package limit for hemp products.
Vermont	 Marijuana regulatory authority oversees hemp products; including chemically converted cannabinoids. Have THC mg serving size and THC per package limit for hemp products. Have age verification in place for certain cannabinoid hemp products.
Virginia	 Virginia Department of Agriculture and Consumer Services may regulate chemically converted cannabinoids included in hemp with recent legislation. Have THC mg serving size and THC per package limit for hemp products. Have age verification in place for certain cannabinoid hemp products.
Washington	 Chemically converted cannabinoids are prohibited.

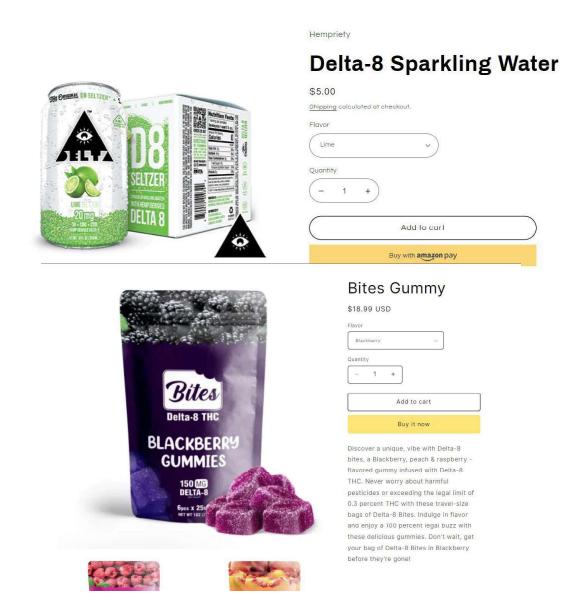
Appendix C – Intoxicating Hemp-derived Products Available in Missouri

Below are examples of intoxicating hemp derived products available at brick-and-mortar hemp retail establishments in Missouri.

The hemp-derived cannabinoids in the Delta-8 THC product examples are created through chemical conversion of other non-intoxicating cannabinoids from hemp, like CBD. Delta-8 THC products may contain unknown solvents and harmful byproducts because of the conversion process.

The hemp-derived cannabinoids in the Delta-9 THC and THCA product examples are the same cannabinoids responsible for the intoxicating qualities of marijuana products. Hemp-derived Delta-9 THC and THCA are made available to consumers outside of DCR's regulatory purview due to the perceived hemp definition "loophole" in the 2018 Farm Bill.

Finally, DCR would find all packaging below appealing to children per 19 CSR 100-1.120(1)(B)1. These products would also be in violation of 195.805 RSMo, which was passed in 2020 to restrict the design of packaging for regulated marijuana edibles to protect children.





Delta 9 Gummies

\$29.99 USD



CBD American Shaman has created a blend of Delta 9 THC that adheres to legal and compliant standards. This blend has been infused into these THC gummies, making them the perfect choice for a night of relaxation. Each gummy contains 12.5mg of Delta 9, providing you with just the right amount for your needs. This variety pack offers four delicious options: Watermelon, Tropical, Blue Raspberry, and Strawberry. For those looking for a lower dosage, the gummies can be cut into quarters or halves, providing 6.25mg or 3.12mg of Delta 9 THC respectively. Everyone has their preferred serving size, but on occasions where you want a stronger experience, you can take 1 or 2 gummies for 12.5mg or 25mg of THC.

All Products Are Hemp Derived And Comply To State of Missouri & Federal Regulations

♦ Home → Delta 9 Edibles → HHH 250MG Delta 9 Compliant 1:1 Dg/CBD Gummies 12.5 mg each gummy



HHH 250MG Delta 9 Compliant 1:1 Dg/CBD Gummies 12.5 mg each gummy

AVAILABILITY : ☑ In stock

PRODUCT TYPE : Edible - Delta 9

\$20.00

All products are hemp derived and comply to State of Missouri and Federal regulations

These products have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.



All Products Are Hemp Derived And Comply To State of Missouri & Federal Regulations

★ Home > THCA Vapes > HHH THC-A 2 Gram Rechargeable Disposable



HHH THC-A 2 Gram Rechargeable Disposable

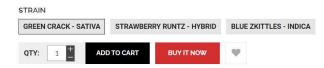
AVAILABILITY : ☑ In stock

PRODUCT TYPE : Vape Disposable - THC-O

\$50.00

All products are hemp derived and comply to State of Missouri and Federal regulations

These products have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.



Resources

- 1. The Agriculture Improvement Act of 2018 (2018 Farm Bill) https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf
- 2. USDA Plants: Hemp https://www.usda.gov/topics/hemp#:~:text=The%20Agriculture%20Improvement%20Act%20of%202018%20(2018%20Farm%20Bill)%20authorized,DEA)%20schedule%20of%20Controlled%20Substances.
- 3. FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD) https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#farmbill
- 4. Health Effects of Marijuana https://www.cdc.gov/marijuana/health-effects/index.html
- 5. U.S. Food and Drug Administration. 5 Things to Know about delta-8 Tetrahydrocannabinol Delta-8 THC. https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc. Published 2022. Accessed February 27, 2024
- 6. CANNRA Cannabinoid Hemp: An Overview https://www.cann-ra.org/s/CANNRA-Hemp-Overview-Long_FINAL.pdf
- 7. CANNRA Cannabinoid Hemp Regulatory Challenges https://www.cann-ra.org/s/Hemp-Regulatory-Challenges-Long-FINAL.pdf
- 8. Considerations in Establishing Cannabinoid Limits for Hemp Products https://www.oregon.gov/olcc/Docs/commission_minutes/2021/Considerations-In-Establishing-Cannabinoid-Limits-Hemp-Whitepaper.pdf
- 9. CANNRA CANNRA Responds to congressional Request for information on federal cannabinoid hemp regulation https://www.cann-ra.org/s/CANNRA-Response-to-Hemp-RFI_FINAL_08172023.pdf
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- 12. FDA Regulation of Cannabis and Cannabis derived products including Cannabidiol (CBD) https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#relatedinfo
- 13. CBD American Shaman Delta 9 Gummies https://americanshamancentralmo.com/products/delta-9-gummies-1
- 14. CBD American Shaman Bites Gummy https://americanshamancentralmo.com/products/bites-gummy
- 15. Hemp Hemp Hooray 250MG Delta 9 Compliant 1:1 D9/CBD Gummies 12.5 mg each gummy https://www.hemphemphooray.com/collections/delta-9-edibles/products/hhh-delta-9-compliant-1-1-d9-cbd-gummies-125mg
- 16. Hemp Hemp Hooray THC-A 2 Gram Rechargeable Disposable https://www.hemphemphooray.com/collections/thca-vapes/products/hhh-thc-a-2-gram-rechargeable-disposable?variant=44939344347413
- 17. Hempriety Delta-8 Sparkling Water https://hempriety.com/products/delta-8-sparkling-water